

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF UTAH
NORTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

RIDLEY’S FAMILY MARKETS, INC.,
Defendant.

MEMORANDUM DECISION AND
ORDER GRANTING IN PART
AND DENYING IN PART
DEFENDANT’S MOTION TO
DISMISS PLAINTIFF’S FIRST
AMENDED COMPLAINT

District Judge Ted Stewart

Case No. 1:20-CV-173-TS-JCB

In this case, the United States seeks civil penalties and injunctive relief against Defendant Ridley’s Family Markets, Inc. (“Ridley’s”) for alleged violations of the Controlled Substances Act (the “CSA”). Now before the Court is Ridley’s Motion to Dismiss Plaintiff’s First Amended Complaint (the “Motion”). The Court will grant the Motion in part and deny it in part.

I. BACKGROUND

Unless otherwise noted, the following facts are alleged in the United States’ Amended Complaint for Civil Penalties and Injunctive Relief (the “Complaint”).¹ Ridley’s owns and operates grocery stores and pharmacies in various states, including a pharmacy inside one of its grocery stores in Morgan, Utah (the “Morgan Pharmacy”). According to the United States, the Morgan Pharmacy filled 160 invalid prescriptions for 16,270 pills for two individuals who were

¹ Docket No. 26.

married to each other. These prescriptions were for carisoprodol, hydrocodone, and oxycodone, which are all controlled substances under the CSA.

The United States alleges that these prescriptions contained several red flags suggesting they might be invalid and that Ridley's pharmacists filled the prescriptions without resolving the red flags. The red flags included cash payments, prescriptions outside the prescriber's normal scope of practice, prescriptions for high doses and long durations, family members living together with similar prescriptions, prescriptions for multiple drugs for the same purpose, "pattern prescribing," early refills, dangerous drug combinations, individuals who authorized their own or their family member's prescriptions, uncommon drug therapies, and facial errors such as misspellings and stamped or forged signatures. Allegedly, Ridley's pharmacists and employees did not fully complete Ridley's Controlled Substance Dispensing Checklist, which identifies some of these red flags. The United States also alleges the pharmacists took no steps to resolve the red flags before filling the prescriptions. The United States complains that this failure violated 21 U.S.C. § 842(a)(1) and § 829 and 21 C.F.R. § 1306.04 and § 1306.06. Thus, the United States seeks civil penalties and injunctive relief.

Ridley's brought this Motion, arguing the Court should dismiss the Complaint in its entirety under Rule 12(b)(6).² The United States submitted a memorandum in opposition on March 5, 2021,³ and Ridley's submitted a reply in support on April 5, 2021.⁴ In addition, the National Association of Chain Drug Stores (the "NACDS") submitted a brief as *amicus curiae* in support of Ridley's Motion on April 14, 2021,⁵ and the United States submitted a response to

² Docket No. 30.

³ Docket No. 31.

⁴ Docket No. 36.

⁵ Docket No. 47.

that brief on April 29, 2021.⁶ The Court also heard oral argument on the Motion on June 1, 2021. Thus, the Motion is ready for resolution.

II. STANDARD OF REVIEW

Under Rule 12(b)(6), a court may dismiss a complaint when it fails to state a claim upon which relief can be granted. “To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face. A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.”⁷ Legal conclusions alone are not sufficient; “they must be supported by factual allegations.”⁸ However, Rule 8 does not require detailed factual allegations.⁹ When reviewing a motion to dismiss, a court must assume all the facts alleged in the complaint are true¹⁰ and view them in the light most favorable to the plaintiff.¹¹ The court must also limit its review to the four corners of the complaint and documents incorporated in the complaint by reference.¹²

III. DISCUSSION

The United States alleges Ridley’s violated the CSA, specifically 21 U.S.C. § 842(a)(1) and § 829, and its implementing regulations, 21 C.F.R. § 1306.04 and § 1306.06. In 21 U.S.C. § 842(a)(1), the CSA prohibits pharmacies from distributing controlled substances in violation of

⁶ Docket No. 49.

⁷ *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citation and internal quotation marks omitted).

⁸ *Id.* at 679.

⁹ *Bell Atl. Corp. v. Twombly*, 550 U.S. 540, 555 (2007).

¹⁰ *Hall v. Bellmon*, 935 F.2d 1106, 1109 (10th Cir. 1991).

¹¹ *Mayfield v. Bethards*, 826 F.3d 1252, 1255 (10th Cir. 2016).

¹² *Smith v. United States*, 561 F.3d 1090, 1098 (10th Cir. 2009); *Mobley v. McCormick*, 40 F.3d 337, 340 (10th Cir. 1994).

21 U.S.C. § 829. In turn, § 829 permits pharmacists to dispense certain controlled substances only with a valid prescription. Regulations in 21 C.F.R. §§ 1306.01–1306.27 articulate the specific rules for issuing and filling prescriptions under § 829. Relevant to this case,

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.¹³

And “[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.”¹⁴ Ridley’s argues that the United States did not sufficiently allege Ridley’s violated 21 C.F.R. § 1306.04(a) or § 1306.06.

A. 21 C.F.R. § 1306.04(a)

Ridley’s contends the United States failed to state a claim under 21 C.F.R. § 1306.04(a) because (1) it failed to adequately allege knowledge and (2) pharmacists are required to fill all facially valid prescriptions.

1. Knowledge

Ridley’s argues the United States failed to adequately allege knowledge because a failure to resolve red flags does not show the pharmacist knew a prescription was invalid. On the contrary, it is well settled that a knowledge requirement can be satisfied by a showing of willful

¹³ 21 C.F.R. § 1306.04(a).

¹⁴ *Id.* § 1306.06.

blindness or deliberate ignorance.¹⁵ “[A] willfully blind [person] is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts.”¹⁶ Willful blindness can be shown through circumstantial evidence such as the existence of and failure to investigate red flags.¹⁷ In addition, courts, including the Tenth Circuit, and the Drug Enforcement Administration have held that pharmacists and pharmacies violated 21 C.F.R. § 1306.04(a) and the CSA when they failed to investigate red flags connected with prescriptions.¹⁸ Here, the United States describes numerous red flags Ridley’s pharmacists encountered and alleges that they failed to investigate these red

¹⁵ *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 767–69 (2011) (referencing “the long history of willful blindness and its wide acceptance in the Federal Judiciary”); *see also United States v. de Francisco-Lopez*, 939 F.2d 1405, 1409 (10th Cir. 1991).

¹⁶ *Global-Tech Appliances*, 563 U.S. at 769.

¹⁷ *de Francisco-Lopez*, 939 F.2d at 1409; *United States v. Otuonye*, 995 F.3d 1191, 1211 (10th Cir. 2021).

¹⁸ *Otuonye*, 995 F.3d at 1211 (affirming a pharmacist’s conviction under 21 U.S.C. § 841(a)(1) because, among other things, he failed to investigate red flags in connection with prescriptions in violation of 21 C.F.R. § 1306.04(a)); *Cherokee Nation v. Mckesson Corp.*, No. CIV-18-056-RAW, 2021 WL 1200093, at *6 (E.D. Okla. Mar. 29, 2021) (“[T]he court concludes that pharmacies, not merely pharmacists, have obligations to ‘resolve red flags’ before dispensing controlled substances concerning suspicious prescriptions.”); *Heartland Pharmacy, Inc. v. Rosen*, No. 21-14037-CV-MIDDLEBROOKS, 2021 WL 650350, at *4 (S.D. Fla. Feb. 18, 2021) (“[P]harmacists violate . . . 21 C.F.R. § 1306.04(a)[] when ‘they fail to identify and resolve the red flags that are part of the prospective drug use review . . .’ and subsequently ‘knowingly fill prescriptions without resolving these red flags during this review.’”) (quoting *Trinity Pharmacy II*, 83 Fed. Reg. 7304, 7329 (Drug Enf’t Admin. Feb. 20, 2018)); *In re Nat’l Prescription Opiate Litig.*, 477 F. Supp. 3d 613, 629 (N.D. Ohio 2020) (“[T]o show a violation of [21 C.F.R. § 1306.04(a)], the Government must establish that: (1) the Respondent [a pharmacy] dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance.”) (quoting *Holiday CVS, L.L.C., d/b/a/ CVS/Pharmacy Nos. 219 and 5195*, 77 Fed. Reg. 62316, 62341 (Drug Enf’t Admin. Oct. 12, 2012); *United States v. City Pharmacy, LLC*, No. 3:16-CV-24 (BAILEY), 2017 WL 1405164, at *4 (N.D.W.V. Apr. 9, 2017) (granting summary judgment against a pharmacist for violating 21 U.S.C. § 842(a)(1) when there was evidence the pharmacist ignored red flags and filled the associated prescriptions).

flags before filling the related prescriptions.¹⁹ These facts sufficiently allege a plausible claim that Ridley’s pharmacists knew of the prescriptions’ invalidity through willful blindness.

Ridley’s also argues the Complaint must identify a specific pharmacist who filled a prescription that he or she knew was illegitimate to satisfy the knowledge requirement. “When considering whether a pharmacy has violated its corresponding responsibility, [a court] considers whether the entity, not the pharmacist, can be charged with the requisite knowledge.”²⁰

“Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself.”²¹ The Complaint meets this requirement by alleging Ridley’s pharmacists and employees filled red flag prescriptions without investigating the prescriptions’ legitimacy.²² Certainly, the Complaint would be stronger if it identified a specific pharmacist who ignored specific red flags connected with a specific prescription. However, the liberal pleading standards do not *require* the United States to identify specific pharmacists or specific prescriptions to state a plausible claim.²³

Ridley’s also argues that a collective knowledge theory—that is, pieces of knowledge that are evaluated cumulatively rather than on the basis of what any individual knows—is not sufficient to establish Ridley’s liability. But the Complaint does not purport to rely on a

¹⁹ Docket No. 26 ¶¶ 42, 44–45, 48–51, 53, 55, 57–61, 63–65, 68–70, 72–73, 75, 78, 80, 82–83.

²⁰ *JM Pharmacy Grp., Inc. d/b/a Farmacia Nueva & Best Pharma Corp.*, 80 Fed. Reg. 28667, 28685 (Drug Enf’t Admin. May 19, 2015).

²¹ *Id.*

²² Docket No. 26 ¶¶ 40, 61, 65, 75, 85–92.

²³ *See In re Nat’l Prescription Opiate Litig.*, 477 F. Supp. 3d at 629 n.25 (explaining that a failure to identify a specific prescription a pharmacy filled that it knew or should have known was illegitimate did not support dismissal at the motion to dismiss stage); Fed. R. Civ. P. 8(a) (requiring only “a short and plain statement of the claim showing that the pleader is entitled to relief”).

collective knowledge theory. Rather, the Complaint alleges that individual Ridley's pharmacists who received, reviewed, and filled the prescriptions at issue knew about and failed to investigate the associated red flags, constituting willful blindness. This individual knowledge may be imputed to the pharmacy without invoking collective knowledge. Thus, the United States has plausibly alleged that Ridley's, through its employees, had knowledge of the illegitimacy of the prescriptions through willful blindness.

2. Facial Validity

Ridley's argues it cannot be liable because pharmacists are required to fill prescriptions that meet all of the facial requirements listed in 21 C.F.R. § 1306.05. This assertion is not supported by any statutes or regulations. Rather, 21 C.F.R. § 1306.04(a) explicitly prohibits pharmacists from filling prescriptions they know are not legitimate regardless of the prescriptions' facial validity. And even if pharmacists have to fill all facially valid prescriptions, the Complaint alleges some of the prescriptions were facially invalid. For example, the United States alleges some of the prescriptions had stamped signatures or "signatures that obviously appear forged, altered, or traced over."²⁴ At this stage, the Court must take these allegations as true, and Ridley's would certainly agree its pharmacists should not have filled facially invalid prescriptions without further investigation. Thus, this argument does not support dismissal.

For these reasons, the Court will deny the Motion as it relates to the United States' claim under 21 C.F.R. § 1306.04(a).

B. 21 C.F.R. § 1306.06

Ridley's contends the Court should dismiss the claim under 21 C.F.R. § 1306.06 for two reasons. Ridley's argues the government's interpretation of § 1306.06 renders § 1306.04(a) and

²⁴ Docket No. 26 ¶ 82.

its knowledge requirement meaningless and undermines the stated administrative intent behind § 1306.04(a). Ridley’s also argues that even if the United States sufficiently stated a claim under § 1306.06, the text of the regulation does not provide for civil penalties. The Court agrees.

When interpreting regulations, courts apply “general rules of statutory construction.”²⁵ This means courts look to the plain language of the regulation, the context of the regulatory scheme, and the administrative intent to determine their meaning. Two regulations are at issue here: 21 C.F.R. § 1306.04(a) and 21 C.F.R. § 1306.06. Section 1306.04(a) prohibits pharmacists from filling prescriptions they know are not legitimate. When a person knowingly fills an illegitimate prescription, it provides that the person “shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” On the other hand, § 1306.06 requires pharmacists to fill prescriptions only “in the usual course of [their] professional practice.” Unlike § 1306.04(a), § 1306.06 does not have a knowledge requirement and does not provide that violators shall be subject to penalties.

In its Complaint, the United States seeks civil penalties and injunctive relief because Ridley’s violated § 1306.06 by “fill[ing] prescriptions without resolving one or more red flags indicating that such prescriptions were not for a legitimate medical purpose or written in the usual course of professional treatment.”²⁶ The Court must determine whether this is sufficient to state a claim under § 1306.06.

As an initial matter, neither the regulations nor the CSA define “the usual course of professional practice.” Thus, the plain text of the regulation alone does not provide sufficient information to determine what is required to state a claim under it. However, unlike §1306.04(a),

²⁵ *Time Warner Entm’t Co., L.P. v. Everest Midwest Licensee, L.L.C.*, 381 F.3d 1039, 1050 (10th Cir. 2004).

²⁶ Docket No. 26 ¶ 102.

§ 1306.06 does not explicitly state that a person who violates the regulation will be subject to the penalties provided under the CSA. Therefore, the Court agrees with Ridley’s that the United States cannot seek civil penalties for a violation under this regulation.

Next, the Court will look to the context of the regulation. Like a statute, a regulatory scheme “generally should be interpreted ‘so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void, or insignificant.’”²⁷ Similarly, “[w]here there is no clear intention otherwise, a specific statute [or regulation] will not be controlled or nullified by a general one.”²⁸ The United States’ claim that Ridley’s violated § 1306.06 has the same basis as its claim that Ridley’s violated 21 C.F.R. § 1306.04(a). To find that this allegation states a claim under both regulations would render § 1306.04(a) and its knowledge requirement meaningless. Essentially, the government could successfully bring a claim against a pharmacist under § 1306.06 for filling prescriptions with red flags even if there was not enough evidence to show the pharmacist had knowledge of their illegitimacy, as required under § 1306.04(a). This goes against general principles of statutory interpretation.

Finally, the Court will consider the clear administrative purpose for the regulations. When it posted the final rule, the agency stated it intentionally included the knowledge requirement in § 1306.04 so that pharmacists would not be responsible “to determine the legitimacy of a prescription.”²⁹ Thus, the United States’ interpretation, which would nullify the

²⁷ *Renewable Fuels Assoc. v. E.P.A.*, 948 F.3d 1206, 1243 (10th Cir. 2020) (quoting *Rubin v. Islamic Republic of Iran*, 138 S. Ct. 816, 824 (2018)); *Silverman v. Eastrich Multiple Inv’r Fund, L.P.*, 51 F.3d 28, 31 (3d Cir. 1995) (applying this canon of statutory interpretation to a regulatory scheme).

²⁸ *Radzanower v. Touche Ross & Co.*, 426 U.S. 148, 153 (1976) (quoting *Morton v. Mancari*, 417 U.S. 535, 550–51 (1974)).

²⁹ Comments and Objections to Part 306, 36 Fed. Reg. 7776, 7777 (April 24, 1971).

knowledge requirement in § 1306.04(a), violates clearly expressed administrative intent.

Furthermore, nullifying the knowledge requirement of § 1306.04(a) would severely interfere with pharmacists' essential jobs, instilling them with fear of penalties when they fill prescriptions for controlled substances. This could ultimately damage patients who need these controlled substances for legitimate medical purposes.

In sum, the plain text, regulatory scheme, and administrative intent all go against the United States' interpretation of § 1306.06. For these reasons, the Court will grant the Motion as to this claim.

IV. CONCLUSION

It is therefore

ORDERED that Ridley's Motion to Dismiss Plaintiff's First Amended Complaint (Docket No. 30) is GRANTED IN PART AND DENIED IN PART as detailed above.

DATED June 7, 2021.

BY THE COURT:

A handwritten signature in black ink, appearing to read "Stewart", with a horizontal line drawn through the middle of the signature.

TED STEWART
United States District Judge